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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,176	03/23/2006	Wolfgang Staehle	MERCK3155	6633

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EXAMINER

OTTON, ALICIA L

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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10/14/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No. 10/573,176	Applicant(s) STAEHLE ET AL.	
	Examiner Alicia L. Otton	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,3,5-11 and 14-38 is/are pending in the application.
- 5a) Of the above claim(s) 14-29 is/are withdrawn from consideration.
- 6) ☒ Claim(s) 7 is/are allowed.
- 7) ☒ Claim(s) 1,3,5,6,9-11 and 30-38 is/are rejected.
- 8) ☒ Claim(s) 8 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 8, 2010 has been entered.

Petition

2. This Office action is responsive to the RCE filed January 3, 2011 with a petition to withdraw the restriction requirement, and follows the decision in the same petition. In view of the petition decision dated September 21, 2011, the requirement for restriction between original groups I and II (now new Group I) and original groups III and IV (now new Group II) is **withdrawn** and instead treated as an election of species requirement. Claims 1, 3, 5-11 and 30-38 remain under consideration in this Office action. The requirement for an election of species in new Group I (i.e. claims 1, 3, 5-11 and 30-38) is withdrawn in view of the fact that the full scope of claim 1 has been searched in accordance with MPEP 803.02. The scope is not found to be allowable for the reasons described herein. Claims 14-29 remain withdrawn from consideration, there being no allowable generic or linking claims. The claims will be considered for rejoinder in accordance with MPEP 821 when the full scope of the linking claim (i.e. claim 1) has been found to be in condition for allowance.

Response to Amendments and Arguments

3. Applicant's arguments and amendments filed December 9, 2010 have been fully considered and entered into the application. All rejections and objections not explicitly maintained herein are withdrawn.

4. Applicant's claim amendments overcome the previous rejection made under 35 U.S.C. 102(e) (over Renhowe et al.); 35 USC 102(b) (over El-Gaby et al.); 35 USC 102(a) (over El-Gaby et al.); and under 35 USC 103(a) (over Renhowe in view of Lind et al.). In accordance with MPEP 803.02, the amended claims will be reexamined and the prior art search extended to the extent necessary to determine patentability of the Markush-type claim. The search was extended to the full scope of Formula (I) as recited in claim 1. This scope is not found to be allowable.

Objections

5. Claim 8 is objected to for being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, including all limitations of the base claim and any intervening claim(s).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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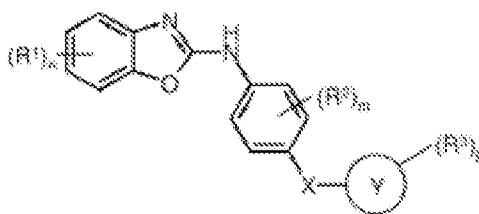
having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

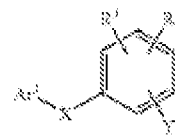
9. Claims 1, 3, 5, 6, 9, 10 and 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,041,691 to McGee et al. Applicant's instant invention is drawn to a

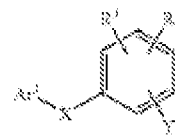


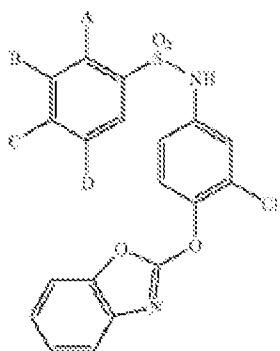
compound of the formula , as well as a pharmaceutical composition and combination thereof.

Determining the scope and contents of the prior art. (See MPEP § 2141.01)

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10. The reference teaches compounds of the formula , where Ar1 is preferably benzoxazole, X can be NH in a list of preferred embodiments, Y is preferably NHSO₂ and R2 is preferably a phenyl group (col. 16, lines 7-24). Most of these preferences are reflected in the compounds embodied in Table 25, Examples 192-195:



Example	A	B	C	D
192	Cl	H	Cl	H
193	Cl	H	Cl	Me
194	Me	H	Cl	Me
195	Cl	H	CF ₃	H

11. The reference also teaches compositions of the prior art compounds at column 21, and the reference further states that other therapeutic agents may also be present (col. 2, ll. 64-5).

Ascertainment of the differences between the prior art and the claims. (See MPEP § 2141.02)

12. The difference between the instant invention and the prior art is that the prior art generically teaches the instantly claimed compounds, where the specific examples of compounds in the prior art differ in that they require an -O- linking group rather than -NH- as required by the instant claims.

Finding of prima facie obviousness --- rationale and motivation (See MPEP § 2141.02)

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13. The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity. There would have been a reasonable expectation of the compounds having this activity since they differ only in a linking group, where the instantly required linking group is both generically encompassed by the prior art, as well as preferred by the prior art (as evidenced by the disclosure of preferred embodiments, as well as the fact that many preferred compounds have an NH linking group. Thus, the reference provides evidence of interchangeability at this position.

14. One skilled in the art at the time the invention was made would thus have been motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as, for example, modulators of PPAR activity. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art at the time the invention was made.

15. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al, US 7,041,691, in view of U.S. Patent No. 6,579,857, published June 17, 2003.

16. Please refer to paragraphs 10-11 above for the relevant teachings of the '691 patent.

17. The '272 reference does not teach a kit of the instantly claimed compound and another active ingredient. However, it is well known in the pharmaceutical art that items can be separated and provided in a kit for the sake of convenience of packaging. The '857 patent states that the unit dose of a particular pharmaceutical agent "is formulated such that the first and

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second compositions are packaged together as a kit, but are not in admixture. A kit that includes each therapeutic agent packaged together in dosage form adds convenience for medical practitioners. Separate packaging of the two compositions permits administration by separate routes, at separate times, and/or at separate rates. Separate packaging also permits formulating each composition uniquely" (see column 9, paragraph 4).

18. Thus it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide the instantly claimed compound and additional active ingredients taught by the '691 patent in the form of a kit in order to conveniently package the formulations so as to allow for either separate or simultaneous administration with unique formulation of compositions, if desired.

Conclusion

19. Claim 7 is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia L. Otton whose telephone number is (571)270-7683. The examiner can normally be reached on Monday - Thursday 8:00-6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated

/Alicia L Otton/
Examiner, Art Unit 1626
/Rebecca L Anderson/

Primary Examiner, Art Unit 1626